

K950550

"This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMMA and 21 CFR §807.92."

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION OF
SUBSTANTIAL EQUIVALENCE ON THE MAIN TECHNICAL FEATURES BETWEEN
THE XH-1 NEUROMUSCULAR STIMULATOR AND
THE MYOPULSE NEUROMUSCULAR STIMULATOR

No.	Item	XH-1, a powered muscle stimulator	Myopulse, a powered muscle stimulator	Level of Safety and Effectiveness
1	Frequency 0.9 Hz	Equivalent	Equivalent	Equivalent
2	Biphasic wave without direct current	Equivalent	Equivalent	Equivalent
3	Wave Form	Similar	Similar	Equivalent
4	Pulse peak output voltage and current, 10,000 ohms load.	+110volts, -110volts. +11mAmp, -11mAmp.	+90volts -115volts. +9mAmp, -11.5mAmp.	Equivalent
5	Output frequency fixed.	Equivalent	Equivalent	Equivalent
6	Output pulse-width fixed under a constant resistant load.	Equivalent	Equivalent	Equivalent
7	Interpulse rest of approximately 1.1 second.	Equivalent	Equivalent	Equivalent
8	@ 0.9 Hz frequency, continuous output	Equivalent	Equivalent	Equivalent
9	Average output current, 10,000 ohms load.	0.18mAmp	0.013 mAmp	Equivalent*
10	Frugal on electrical consumption	Two AA batteries, 3volts, can operate for 700 hours.	One 9volt batter. can operate for 350 hours.	Equivalent
11	Electrode Coupling Medium	Paper towel moistened with water.	Sponge moistened with water.	Equivalent
12	Function: to relax muscle spasm	Equivalent	Equivalent	Equivalent
13	History of clinical usage	Since 1987 to present	Since 1968 to present	Equivalent
14	Adverse effects are not known.	Equivalent	Equivalent	Equivalent

*Dangerous current levels are those above about 15 milliamps, but below 1 milliamp is considered completely safe to the human body according to the Federal Engineering department associated with the National Electric Code and according to the State of California OSHA Consultation Group.

The 14 main technical features in the summary prove that the XH-1 Neuromuscular Stimulator is substantially equivalent, in terms of safety and effectiveness, to the Myopulse Neuromuscular Stimulator, which is a preamendment device marketed prior to May 28, 1976.

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January 17, 1995

COMPARISON CHART OF THE SIMILARITIES OF MAIN TECHNICAL
FEATURES BETWEEN THE XH-1 NEUROMUSCULAR STIMULATOR
AND OTHER ELECTRICAL MUSCLE STIMULATORS WITH 510(K) NUMBER

No.	Item	XH-1	Other Products
1	Neuromuscular Stimulator as proprietary name	Equivalent	Those with equivalent proprietary names: K840346 K926510
2	Frequency of 1 Hz	0.9 Hz	Those that "can" be <u>adjusted</u> to 1 Hz output: K850013 K893878 K893879
3	Interpulse resting time of approximately 1 second	1.1 second	Those that can be adjusted to 1-second off time: K893878 K893879 K926510
4	Pulses with continuous output	At 0.9 Hz, continuous output	Those that <u>can</u> be adjusted to continuous output: K840346 K926510

not same as device having only a 1 Hz output.

"can" have continuous output

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January, 1995